Please amend the Claims as shown in the marked up version of the Claims accompanying this Reply, resulting in the Claims as set fortn in the clean copy. In particular, the requested changes include:

a. Cancel claims 1-8 and 17.

b. Modify claims 9 - 16 and 18 by adding and deleting as shown in the marked up version.

REMARKS

Claims 1 - 8 and 17 have been cancelled. Claims 9 - 16 and 18 remain in the application.

Applicant hereby requests further examination and reconsideration of the application, in view of the foregoing amendments.

Drawings

New drawings accompany this Reply, to overcome the objections set forth in the Office Action. Pages 4 and 5 of the Specification have been amended to properly refer to the new drawings. No new matter has been added, as each element shown in the drawings was described in the original Specification.

Section 102 Rejections

Claims 1, 9 and 16-18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Keeton. Claims 1 and 17 have been cancelled. Claim 9 has been amended, effectively amending claims 10 - 14 which depend on Claim 9. Claims 15, 16, and 18 have also been amended.

Claim 9 has been amended to limit the claimed device in two ways. First, the visually perceivable indicator is required "to warn against surgery on the body segment" to which the device is attached. Support for this limitation is found throughout the claims, and in particular in the last paragraph of page 3 of the original Specification. Such a warning message is neither anticipated by the prior art nor rendered unobvious.

Keeton describes a surgical gown which may include a label directing a surgeon to operate on a particular body part (see Keeton, column 2, lines 30-32). In contrast, the amended claims of the instant application expressly require an indicator which directs a surgeon NOT to operate on a particular body segment. This visual indicator provides a message which is significantly more likely to prevent wrong-site surgery than devices available in the prior art.

For example, a patient may be scheduled for surgery on a right knee. If an error is made in the patient's chart, or if the surgeon incorrectly interprets the chart, the surgeon may prepare to operate on the patient's left knee. In this situation, if the patient has utilized Keeton's gown to identify the correct surgical site, *the surgeon may never look at the right knee, which is necessary to see the Keeton-type label identifying the correct surgery site*. Since the surgeon intends to operate on the left knee, the surgeon is unlikely to look at the right knee, and thus would be oblivious to a Keeton-type device. In contrast, use of the device claimed in instant claim 9, as amended, would result in a visually perceivable warning placed on the patient's left knee, with a warning against surgery on that body part. It can be appreciated that such a device is not anticipated by Keeton, and is more likely to be noticed by the surgeon than a Keeton-type device, and thus more likely to protect against wrong-site surgery.

Secondly, claim 9 has been amended to require the claimed device to be attached to a body segment which is not to be affected by surgery, in a manner which permits the device to be removed after surgery. Support for this limitation is found throughout the

specification, and in particular the next to the last paragraph of page 3 of the original specification.

Keeton teaches a gown which is *intended to be cut away from a patient during a surgical procedure* (see Keeton, column 2, lines 29-30). Since any label indicating a surgical site is intended to be incorporated into that gown, it is most likely that a *Keeton-type label would be removed prior to a surgical procedure*, as the gown is taken apart to allow cutting of a body segment. In contrast, amended claim 9 and all claims depending on it require a device which is removable after a surgical procedure has been concluded. In this manner, the warning against wrong-site surgery is kept in place throughout the perioperative period, both prior to (preoperatively) and throughout (intraoperatively) surgery, in a manner unanticipated by Keeton. In fact, the claimed device can also be applied to the patient well before the surgical theater, as opposed to being administered only when a surgical gown is donned. Thus, the claimed device provides an effective warning against wrong-site surgery throughout pre-operative procedures, prior to any gown or draping being applied to the patient, during surgery, and even postoperatively such as during a recovery period.

This distinction is further stressed by amendments to claim 15. The method described in claim 15 contains all of the limitations of claim 9, and has been further amended to require the claimed strip to be removed from a patient's body segment *after the surgical procedure has been concluded.* This is significantly different from Keeton which anticipates removal of a portion of the gown bearing the label prior to cutting a body segment.

Amended claim 16 requires the use of a system which includes both a device to warn against surgery in an incorrect site and a device to identify a surgical site. This system necessarily includes the device to warn against wrong-site surgery which is described and limited in the same terms as the device described in amended claim 9.

Amended claim 18 requires the use of an applique, such as a temporary tattoo, which warns against wrong-site surgery. As with the device claimed in claim 9, the device of claim 18 is not anticipated nor made obvious by Keeton because it warns against surgery in a particular body segment and cannot be removed during a surgical procedure.

Section 103 Rejections

Claims 2 - 8 and 10 - 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Keeton in view of De Woskin. Claims 2 - 8 have been cancelled. Claims 10 - 15 have been amended by amendment of the claims on which they depend.

Claims 10 - 14 depend on Claim 9, and thus are subject to the limitations of claim 9. For reasons set forth above, it is submitted that claim 9 is not obvious given the limitations added to that claim by the instant Reply. Since those limitations are incorporated into claims 10 - 14, it is submitted that those claims are also non-obvious.

Additional References

Weaver discloses a warning device for a particular medical condition, lymphedema, and is not used during surgery. It should be noted that the filing date of Weaver, February 15, 2000, is later in time than the filing date of the provisional application associated with the instant application, which was December 6, 1999.

In view of the above, it is submitted that the claims are in condition for allowance.

Allowance of claims 9 - 16 and 18 at an early date is solicited.

Respectfully submitted,

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I claim:

~~1. A pre-surgical safety, warning, notification, and/or alerting device or system comprising, in combination, an effectively shaped topical pre-printed or diagrammed warning strip.~~

~~2. A pre-surgical safety, warning, notification, and/or alerting device or system as described in Claim 1, including, in combination, an adhesive strip.~~

~~3. A pre-surgical safety warning, notification, and/or alerting device or system as described in Claim 1, wherein the notification agent is placed onto an adhesive surface.~~

~~4. A method for pre-surgically warning, notifying and/or alerting the surgical health care provider(s) that they are not at the intended surgical site, comprising the steps of:~~

~~forming a pre-surgical safety warning, notification, and/or alerting device or system in combination with an adhesive strip or surface and applying the safety, warning, notification, and/or alerting device or system topically at a location that alerts the surgical health care provider(s) that they are not at the intended surgical site.~~

~~5. A method as defined in Claim 4 wherein:~~

~~the pre-surgical safety, warning, notification, and/or alerting device or system is attached to an adhesive surface, and topically applying the adhesive surface at a location that alerts the surgical health care provider(s) that they are not at the intended surgical site.~~

~~6. A method as defined in Claim 5 further comprising:~~

~~leaving the pre-surgical safety, warning, notification, and or alerting device or system on the skin for a predetermined sufficient amount of time for complete, unambiguous pre-surgical identification of the impending surgical site as not being the intended surgical site.~~

~~7. A method as defined in Claim 6 further comprising an adhesive surface with an effective amount of a vinyl, PVC, cellulose, woven filament, fabric or other material of various sizes and shapes as a pre-printed surface.~~

~~8. A pre-surgical safety, warning, notification, and/or alerting device or system for topical application to the skin, comprising:~~

~~a pre-surgical safety, warning, notification, and/or alerting device or system, pre-printed and diagrammed; and an adhesive surface onto which the pre-surgical safety warning, notification, alerting device or system can be affixed for topical application to the skin and holding the pre-surgical safety, warning, notification, and/or alerting device or system in contact with a patient's skin at an unintended surgical site.~~

9. A pre-surgical alerting device comprising:

a. a strip suitable for placing on a body segment which is not to be affected by a surgical procedure, said strip having a superior side and inferior side,

b. visually perceivable indicator to warn against surgery on the body segment on said superior side, and

c. temporary attachment means for temporarily attaching said inferior side to the body segment in a manner which permits said strip to be removed after the surgical procedure. (amended)

10. A pre-surgical alerting device according to claim 9~~1~~, wherein said attachment means comprises an adhesive. (amended)

11. A pre-surgical alerting device according to claim 9~~1~~, wherein said strip is perforated to allow oxygen to diffuse to skin to which the strip is attached. (amended)

12. A pre-surgical alerting device according to claim 9~~1~~, wherein said visually perceivable indicator comprises the words "No Cut". (amended)

13. A pre-surgical alerting device according to claim 10~~2~~, further comprising peelable backing affixed to said inferior side to cover said adhesive when said device is not in use. (amended)

14. A pre-surgical alerting device according to claim 9~~1~~, further comprising a companion label suitable for detaching from said strip and for attaching to a patient's medical chart to indicate use of the alerting device. (amended)

15. A pre-surgical alerting method, comprising the steps of:

a. applying a visually perceivable indicator to warn against surgery on a body segment to a superior side of a strip,

b. topically applying an inferior side of said strip to ~~a~~ the body segment which is not to be affected by a surgical procedure, ~~and~~

c. temporarily affixing said strip to said body segment in a manner which permits said strip to be removed after the surgical procedure, and

d. removing said strip from said body segment after the surgical procedure is concluded. (amended)

16. A pre-surgical alerting ~~device~~ system comprising:

a. ~~an alerting~~ notification strip suitable for placing on an involved body segment which is to be affected by a surgical procedure, said ~~alerting~~ notification strip having ~~a~~ superior side and inferior side,

b. visually perceivable indicator to indicate surgical site on said superior side of said ~~alerting~~ notification strip, ~~and~~

c. temporary attachment means for temporarily attaching said inferior side of said ~~alerting~~ notification strip to the involved body segment,

d. a warning strip suitable for placing on a body segment which is not to be affected by a surgical procedure, said warning strip having a superior side and inferior side,

e. visually perceivable indicator to warn against surgery on the body segment on said superior side, and

f. temporary attachment means for temporarily attaching said inferior side to the body segment in a manner which permits said warning strip to be removed after the surgical procedure. (amended)

~~17. A pre-surgical alerting device according to claim 16, further comprising:~~

~~d. a warning strip suitable for placing on a not-involved body segment which is not to be affected by a surgical procedure, said warning strip having a superior side and inferior side,~~

~~b. visually perceivable indicator on said superior side of said warning strip, and~~

~~c. temporary attachment means for temporarily attaching said inferior side of said warning strip to the not-involved body segment.~~

18. A pre-surgical alerting method, comprising the steps of:

applying a skin-penetrative applique of a message warning against surgery ~~concerning an appropriate location for surgery~~ to a body segment which is not to be affected by surgery. (amended)

The within invention is distinguishable from prior art in that the primary purpose and embodiment of the invention is as a pre-surgical safety, warning, notification, and/or alerting device, intended to alert surgical health care providers that they are **NOT** at the intended surgical site.

2. DISCLOSURE OF THE INVENTION

2.1 SUMMARY OF THE INVENTION

An object of this invention is to provide a novel pre-surgical method of providing safety, warning, notification and/or alerting device, intended to help avoid accidental surgical procedures from being performed on patients' unintended limbs, tissue and/or other body parts.

2.2 BRIEF DESCRIPTION OF THE DRAWINGS ~~(PHOTOGRAPH)~~

~~A frontal view of the invention is attached.~~

FIG. 1 is a front view of a pre-surgical alerting device, according to the present invention.

FIG. 2 is a view of both sides of a pre-surgical alerting device, according to the present invention.

FIG. 3 is a front view of another pre-surgical alerting device, according to the present invention.

FIG. 4 is a front view of a pre-surgical alerting and notifying system, according to the present invention.

2.3 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention concerns a ~~new and~~ novel method of providing a pre-surgical safety, warning, notification, and/or alerting device to help avoid

surgical procedures from being accidentally performed on patients' unintended limbs, tissue and/or other body parts.

In the following description, numerous specific details are set forth in order to provide thorough understanding of the present invention. It will be obvious, however, to one skilled in the art that the present invention may be practiced without these specific details. Some well-known methods and structures have not been set forth in order not to unnecessarily obscure the description of the present invention.

The preferred embodiment of the invention includes a vinyl, PVC, cellulose, woven filament, fabric or other material strip 10 of various sizes (e.g. 2 inches by 3 inches) and/or shapes (rectangle, square, round or other) in various color combinations (red, white, etc.). As shown in Figure 1, ~~T~~the strip 10 may be constructed of material ~~may be perforated~~ with perforations 20 to allow oxygen to diffuse to the underlying skin. Such a strip 10 may be ~~and is~~ similar in construction to bandage wound care products without the wound pad. Alternatively, as shown in Figure 3, a skin-penetrative appliqué 30 such as a temporary tattoo may be attached to a patient as the vehicle for alerting health care providers to a site which is not intended for a medical procedure. The ~~invention~~ strip 10 is intended to remain in place for between 24 to 48 hours.

Words, pictorial images, and/or other warning message(s) 16 are printed on the superior ~~(upper/outer)~~ side 12 of the strip 10. As best shown in Figure 2, ~~T~~the inferior ~~(bottom/under)~~ side 14 of the strip 10 is coated with adhesive 18, ~~(~~similar to that customarily used on bandage wound care products. In this manner, the strip 10 can be~~) to~~ affixed ~~the invention~~ to the skin of a patient prior to surgery or other medical procedure. Non-stick peelable backing 22 is affixed to the inferior side 14 of the ~~invention~~ strip 10 and is intended to be removed prior to use. The invention is/may be packaged in a sterile sleeve envelope or on a continuous roll (not shown).

The ~~invention~~ strip 10 may be affixed to the patient pre-surgically by the patient, physician, and/or other health care provider. The invention may beneficially includes a companion label 24 which is a miniature version of the ~~invention~~strip 10.~~,~~ The companion label 24 is intended to be affixed to the patient's medical chart (not shown) to document that the ~~invention~~ alerting strip 10 has been utilized and has been affixed to pertinent or appropriate area(s) of the patient in order to warn the surgical health care

provider(s) that they are not at the intended surgical site. As shown in Figure 1, identical numbers 28 on both the alerting strip 10 and the companion label 24 establish that a particular strip 10 is related to the companion label 24 with the corresponding numeral 28.

As shown in Figure 4, a system comprising an alerting strip 10 and a corresponding strip 26 may be used, to establish with certainty the appropriate location for a medical procedure. When the system shown in Figure 4 is used, the alerting strip 10 is attached to an area of the patient's body which should not be effected by a surgical procedure. The corresponding strip 26 is purposely attached to the area of the patient's body which should be effected by the surgical procedure, and provides notice of the proper surgical site by a visual indicator. The visual indicator of the corresponding strip 26 can be as simple as the words "CUT HERE", although it will be understood that other indicators can also be used.

The foregoing constitute the best mode known by the applicant for carrying out this invention; however, the specific embodiments disclosed are illustrative of the principle of the invention and are not limiting in scope. To the contrary, it is recognized that one of ordinary skill in the art, given this teaching, may make variations in the structure or compositions without departing from the spirit and scope of this invention. Its scope is defined by the following claims including the protection offered by the doctrine of equivalents.